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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/824,740	04/15/2004		Willa Fabian	P-9621.05	7058	
27581	7590	06/12/2006		EXAMINER		
MEDTRONIC, INC.				LAYNO, CARL	LAYNO, CARL HERNANDZ	
710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924				ART UNIT	PAPER NUMBER	
			•	3766		

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Application No. Applicant(s)					
•	Office Action Con	10/824,740	FABIAN ET AL.					
	Office Action Summary	Examiner	Art Unit					
		Carl H. Layno	3766					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1) 又	Responsive to communication(s) filed or	n <i>03 <u>April 2006</u>.</i>						
	•	☐ This action is non-final.						
3)	Since this application is in condition for a	allowance except for formal	matters, prosecution as to the	e merits is				
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims								
4) 🛛	4) Claim(s) 1,2 and 6-11 is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)	5) Claim(s) is/are allowed.							
6)⊠	)⊠ Claim(s) <u>1,2,6,7,9 and 10</u> is/are rejected.							
•	Claim(s) <u>5 and 8</u> is/are objected to.							
8) Claim(s) are subject to restriction and/or election requirement.								
Applicati	on Papers	•						
9) The specification is objected to by the Examiner.								
10)⊠ The drawing(s) filed on <u>15 April 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority (	ınder 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> </ul>								
2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage								
application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
Attachmen	t(s)							
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)								
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152) 6) Other:								

Application/Control Number: 10/824,740 Page 2

Art Unit: 3766

#### **DETAILED ACTION**

1. Acknowledgment is made of applicant's amendment, which was received by the Office on April 3, 2006.

2. Claims 3 and 4 are canceled. Claims 1, 2, and 5-11 are active.

## Claim Rejections - 35 USC § 112

3. In view of applicant's modifications to claim 11, the Examiner is withdrawing the 35 U.S.C 112 rejection, which was made against this claim in the last Office action.

# Claim Rejections - 35 USC § 102

- 4. Upon further reconsideration of applicant's arguments and amendments to the claims, the Examiner is withdrawing the 35 U.S.C 102(e) rejection of Christopherson et al (US 6,805,667), which was made against claims 1, 3, 5, and 11 in the last Office action.
- 5. Applicant's arguments with respect to claims 1, 6, 7, 9, and 10 have been considered but are most in view of the new ground(s) of rejection.
- 6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1, 2, 6, 9, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Teller et al (US 2002/0019586 A1).

In regard to claims 1, 6, 9, and 11, the Teller et al (US 2002/0019586 A1) U.S. Patent Application Publication discloses a system for monitoring health, wellness, and fitness of an individual. The system (Fig.1) includes a wireless device 50 with attached sensor 10. The wireless device may be implanted in the body (paragraph [0114], lines 5-11) and could be any number of devices including a pacemaker and drug pump, such as the Medtronic MiniMed<sup>TM</sup>. These sensing devices communicate wirelessly to a home monitoring system in the form of a personal computer 35 (Fig.1). The computer 35 also communicates bi-directionally via the

Application/Control Number: 10/824,740

Art Unit: 3766

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Internet to a remotely located Central Monitoring Unit 30, which performs the function of applicant's "remote expert station". In use, a patient working on computer 35 has access via the Internet to a Health Manager web page (Figs.5-11 and paragraph [0008], lines 4-6), which gives a visual feedback of their physical condition (paragraphs [0072] and [0074]). In addition, the computer (also shown in Fig.20) has the capability of giving audible feedback to the user in the form of a ringer 575 (paragraph [0115]), whose activation may be indicative of a variety of feedback messages.

In regard to claims 1 and 2, the Health Manager web page 150 (Fig.5) tracks 6 indicators of a patient's lifestyle (paragraph [0074], lines 6-8). These are Nutrition, Sleep, Activity Level, Daily Activities, Mind Centering, and How You Feel.

In regard to claim 6, the Nutrition category, which is tracked by the device of Teller et al includes information on the duration of breakfast, lunch, and dinner of a patient as well as, the kind of food consumed.

In regard to claim 9, the apparatus may also include "a component to enable the manual entry of information" (paragraph [0019], lines 27-28).

In regard to claim 11, the "at least one implanted device" is a pacemaker (paragraph [0114], lines 7-8).

8. Claims 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Combs et al (US 5,957,861).

In regard to claims 7 and 10, the Combs et al (US 5,957,861) patent describes an impedance monitoring system (Fig.6) comprising implanted devices **OD** and **ID** in wireless

Art Unit: 3766

communication with a home monitoring device **D1** (col.13, lines 43-45) via a wearable device **WD** for discerning edema in a patient. The patient physiological data received by device **D1** may then be transmitted over the telephone lines to a remotely located physician station or hospital **D3** (col.13, lines 49-54). If the system senses a combination of impedance and respiratory rates indicative of a dangerous edema, an alarm is generated (Fig.11 - block **11e**) and at the same time a visual indication is displayed via a readout of stored data (Fig.11- block **11f**). The alarm may be an audible indication or vibratory (col.16, lines 46-47).

In regard to claim 7, in response to the detection of edema, the Combs et al system, if implanted in a drug pump, can be used to "alter the delivery of drugs and stimulation pulses to respond to the onset of edema automatically" (col.4, lines 1-4). The home monitor **D3** controls the trigger release values for controlling the amount of drug dispensed from the drug pump (col.13, lines 52-58).

In regard to claim 10, the system of Combs et al records Long Term Average (LTA) and Short Term Average (STA) values representative of edema in memory (Abstract, lines 4-6). This "trend data" is charted over time to identify variations, which may be of diagnostic value to a physician (col.11, lines 32-36).

9. Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by Warkentin et al (US 6,471,645).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The Warkentin et al (US 6,471,645) patent describes a communications system for controlling an implantable medical device and drug dispenser. Applicant's attention is directed to Fig.1 which shows an implanted medical device 10 in wireless communication with a "home monitoring system" comprising a programmer w/display 20 and web based pill dispenser 20'. These devices provide bi-directional real-time data, sound and video communications between the patient using programmer 20 and a remote web-based expert data center 62,62' via the Internet (col.4, lines 46-55).

### Claim Rejections - 35 USC § 103

10. Upon further reconsideration of applicant's arguments and amendments to the claims, the Examiner is withdrawing the 35 U.S.C 103(a) rejection of Webb et al (US 6,599,250) or Scarantino et al (US 6,402,689) in view of Greeninger et al (US H1347), which was made against claims 1 and 8 in the last Office action.

# Double Patenting

11. Upon further reconsideration of applicant's amendments to claim 1, the Examiner is withdrawing the Double Patenting rejection, which was made against claims 1, 2, and 11 in the last Office action. The claims are no longer similar since the claim now includes the limitations of processing "multiple inputs" including "lifestyle information".

Application/Control Number: 10/824,740 Page 7

Art Unit: 3766

#### Allowable Subject Matter

12. Claims 5 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/824,740

Art Unit: 3766

CARL LAYNO
PRIMARY EXAMINER

CHL 6/6/2006